



Food and Drug Administration
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July 8, 2015

Aesculap, Inc.
% Denise Adams
Regulatory Affairs Specialist
3773 Corporate Parkway
Center Valley, PA 18034

Re: K142970
Trade/Device Name: SterilContainer S System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: June 9, 2015
Received: June 10, 2015

Dear Ms. Adams,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K142970

Device Name
SterilContainer S System

Indications for Use (Describe)

The SterilContainer S System is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and single-use polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container system has been validated with hinged, and knurled instruments. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with STERRAD 100NX EXPRESS Cycle. The SterilContainer S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

Testing has been completed on the SterilContainer S Full size container to maintain the sterility of its contents for 360 days following successful sterilization.

Testing has been completed on the SterilContainer S ½ size container to maintain the sterility of its contents for 30 days following successful sterilization.

The validated chamber load for the SterilContainer S Full and Half sizes in the STERRAD 100NX EXPRESS Cycle consisted of one SterilContainer S placed on the bottom shelf in an otherwise empty chamber.

SterilContainer S Compatible Containers in STERRAD 100NX EXPRESS Cycle

Lid	Bottom	Description	Total loaded container weight (lbs)	Intended load
JM489	JM440	Full Size 90mm (4 ¼")	25.0	reusable metal and non-metal medical devices without lumens including endoscopes without lumens OR the da Vinci Scope Platform (MD425) and two Si or S series da Vinci Scopes
	JM441	Full Size 120mm (5 ½")	25.0	
	JM442	Full Size 135mm (6")	25.0	
	JM444	Full Size 187mm (8")	25.0	
JM389	JM340	½ Size 90mm (4 ¼")	21.2	reusable metal and non-metal medical devices without lumens including endoscopes without lumens
	JM341	½ Size 120mm (5 ½")	21.5	
	JM342	½ Size 135mm (6")	21.7	
	JM344	½ Size 187mm (8")	22.2	

STERRAD 100NX EXPRESS Cycle Compatible SterilContainer S System Accessories

Accessories	STERRAD 100NX EXPRESS Cycle
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes
Silicone mats	Yes
Stainless Steel racks, trays, holders, clamps, brackets, and platforms	Yes

Type of Use (*Select one or both, as applicable*)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY (as required by 21 CFR 807.92)

SterilContainer™ S System

June 29, 2015

COMPANY: Aesculap, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Denise R. Adams
610-984-9076 (phone)
610-791-6882 (fax)

TRADE NAME: SterilContainer S System

COMMON NAME: Sterilization Container

CLASSIFICATION NAME: Sterilization Wrap

PRODUCT CODE: KCT

DEVICE CLASS: Class II per 21 CFR §880.6850

SUBSTANTIAL EQUIVALENCE

Aesculap, Inc. believes that the SterilContainer S System for use in the STERRAD 100NX EXPRESS Cycle is substantially equivalent to Aesculap SterilContainer S for use in STERRAD 200, NX (Standard and Advanced Cycles), and 100NX (Standard and Flex Cycles) cleared via K093493.

DEVICE DESCRIPTION

The SterilContainer S System is a container system that will allow for sterilization and storage of medical devices. This container system is for use in low-temperature sterilization technology such as with the STERRAD 100NX EXPRESS Cycle. The SterilContainer S System rigid containers are made from non-anodized Aluminum and utilize disposable (single use) polypropylene filters. The SterilContainer S System includes accessories such as mats, baskets, trays, holders, organizers, filters, indicator cards and tamper-evident locks.

INDICATIONS FOR USE

The SterilContainer *S* System is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and single-use polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container system has been validated with hinged, and knurled instruments. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with STERRAD 100NX EXPRESS Cycle. The SterilContainer *S* System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.

Testing has been completed on the SterilContainer *S* Full size container to maintain the sterility of its contents for 360 days following successful sterilization.

Testing has been completed on the SterilContainer *S* ½ size container to maintain the sterility of its contents for 30 days following successful sterilization.

The validated chamber load for the SterilContainer *S* Full and Half sizes in the STERRAD 100NX EXPRESS Cycle consisted of one SterilContainer *S* placed on the bottom shelf in an otherwise empty chamber.

SterilContainer *S* Compatible Containers in STERRAD 100NX EXPRESS Cycle

Lid	Bottom	Description	Total loaded container weight (lbs)	Intended load
JM489	JM440	Full Size 90mm (4 ¼")	25.0	reusable metal and non-metal medical devices without lumens including endoscopes without lumens OR the da Vinci Scope Platform (MD425) and two Si or S series da Vinci Scopes
	JM441	Full Size 120mm (5 ½")	25.0	
	JM442	Full Size 135mm (6")	25.0	
	JM444	Full Size 187mm (8")	25.0	
JM389	JM340	½ Size 90mm (4 ¼")	21.2	reusable metal and non-metal medical devices without lumens including endoscopes without lumens
	JM341	½ Size 120mm (5 ½")	21.5	
	JM342	½ Size 135mm (6")	21.7	
	JM344	½ Size 187mm (8")	22.2	

STERRAD 100NX EXPRESS Cycle Compatible SterilContainer *S* System Accessories

Accessories	STERRAD 100NX EXPRESS Cycle
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes
Silicone mats	Yes
Stainless Steel racks, trays, holders, clamps, brackets, and platforms	Yes

TECHNOLOGICAL CHARACTERISTICS (compared to predicates)

The SterilContainer S System is for use in low-temperature sterilization technology such as the STERRAD 100NX EXPRESS Cycle. The SterilContainer S System is the same container system as was cleared in K093493. The materials and design have not changed.

System	SterilContainer S (K142970)	SterilContainer S (K093493)																																																																																													
Indications for Use	<p>The SterilContainer S System is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and single-use polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container system has been validated with hinged, and knurled instruments. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with STERRAD 100NX EXPRESS Cycle. The SterilContainer S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.</p> <p>Testing has been completed on the SterilContainer S Full size container to maintain the sterility of its contents for 360 days following successful sterilization.</p> <p>Testing has been completed on the SterilContainer S ½ size container maintain the sterility of its contents for 30 days following successful sterilization.</p> <p>The validated chamber load for the SterilContainer S Full and Half sizes in the STERRAD 100NX EXPRESS Cycle consisted of one SterilContainer S placed on the bottom shelf in an otherwise empty chamber.</p> <p>SterilContainer S Compatible Containers in STERRAD 100NX EXPRESS Cycle</p> <table><tr><th>Lid</th><th>Bottom</th><th>Description</th><th>Total loaded container weight (lbs)</th><th>Intended load</th></tr><tr><td rowspan="4">JM489</td><td>JM440</td><td>Full Size Perforated Bottom 90mm (4 ¼")</td><td>25.0</td><td rowspan="4">reusable metal and non-metal medical devices without lumens including endoscopes without lumens OR the da Vinci Scope Platform (MD425) and two Si or S series da Vinci Scopes</td></tr><tr><td>JM441</td><td>Full Size Perforated Bottom 120mm (5 ½")</td><td>25.0</td></tr><tr><td>JM442</td><td>Full Size Perforated Bottom 135mm (6")</td><td>25.0</td></tr><tr><td>JM444</td><td>Full Size Perforated Bottom 187mm (8")</td><td>25.0</td></tr><tr><td rowspan="4">JM389</td><td>JM340</td><td>½ Size Perforated Bottom 90mm (4 ¼")</td><td>21.2</td><td rowspan="4">reusable metal and non-metal medical devices without lumens including endoscopes without lumens</td></tr><tr><td>JM341</td><td>½ Size Perforated Bottom 120mm (5 ½")</td><td>21.5</td></tr><tr><td>JM342</td><td>½ Size Perforated Bottom 135mm (6")</td><td>21.7</td></tr><tr><td>JM344</td><td>½ Size Perforated Bottom 187mm (8")</td><td>22.2</td></tr></table> <p>STERRAD 100NX EXPRESS Cycle Compatible</p>	Lid	Bottom	Description	Total loaded container weight (lbs)	Intended load	JM489	JM440	Full Size Perforated Bottom 90mm (4 ¼")	25.0	reusable metal and non-metal medical devices without lumens including endoscopes without lumens OR the da Vinci Scope Platform (MD425) and two Si or S series da Vinci Scopes	JM441	Full Size Perforated Bottom 120mm (5 ½")	25.0	JM442	Full Size Perforated Bottom 135mm (6")	25.0	JM444	Full Size Perforated Bottom 187mm (8")	25.0	JM389	JM340	½ Size Perforated Bottom 90mm (4 ¼")	21.2	reusable metal and non-metal medical devices without lumens including endoscopes without lumens	JM341	½ Size Perforated Bottom 120mm (5 ½")	21.5	JM342	½ Size Perforated Bottom 135mm (6")	21.7	JM344	½ Size Perforated Bottom 187mm (8")	22.2	<p>The Aesculap Sterilcontainer S is a reusable sterilization container system (consisting of perforated bottoms and perforated lids with filter retention plates, and disposable polypropylene filters) intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. This container has been validated with stainless steel lumens, hinged, and knurled instruments. It is intended to allow sterilization of the enclosed device and also maintain sterility of the enclosed device until used. This container system is compatible for use with the STERRAD 200, STERRAD NX (Standard cycle and Advanced cycle), and STERRAD 100NX (Standard cycle and Flex cycle). The Sterilcontainer S System includes accessories such as silicone mats, baskets, trays, racks, eyepiece holders and sleeve holders.</p> <p>The Sterilcontainer S is recommended for surface and lumens:</p> <p>STERRAD 200, stainless steel lumens ≥ 3mm I.D. x ≤ 400mm L STERRAD NX standard cycle, stainless steel lumens ≥ 2mm I.D. x ≤ 400mm L STERRAD NX advanced cycle, stainless steel lumens ≥ 1mm I.D. x ≤ 500mm L STERRAD 100NX standard cycle, stainless steel lumens ≥ 0.7mm I.D. x ≤ 500mm L STERRAD 100NX flex cycle, porous lumens (flexible endoscope) ≥ 1mm I.D. x ≤ 850mm L</p> <p>30 days of shelf life testing has been conducted for the Sterilcontainer S.</p> <p>TABLE 1: SterilContainer S Compatible Containers in STERRAD 200</p> <table><tr><th>Item #</th><th>Description</th><th>Total loaded container weight (lbs)</th></tr><tr><td>JM440</td><td>Full Size Perforated Bottom 90mm (4 ¼")</td><td>21.46</td></tr><tr><td>JM441</td><td>Full Size Perforated Bottom 120mm (5 ½")</td><td>21.46</td></tr><tr><td>JM442</td><td>Full Size Perforated Bottom 135mm (6")</td><td>21.46</td></tr><tr><td>JM444</td><td>Full Size Perforated Bottom 187mm (8")</td><td>21.46</td></tr><tr><td>JM740</td><td>¾ Size Perforated Bottom 90mm(4 ¼")</td><td>14.42</td></tr><tr><td>JM741</td><td>¾ Size Perforated Bottom 120mm (5 ½")</td><td>14.42</td></tr><tr><td>JM742</td><td>¾ Size Perforated Bottom 135mm (6")</td><td>14.42</td></tr><tr><td>JM340</td><td>½ Size Perforated Bottom 90mm (4 ¼")</td><td>14.42</td></tr><tr><td>JM341</td><td>½ Size Perforated Bottom 120mm (5 ½")</td><td>14.42</td></tr><tr><td>JM342</td><td>½ Size Perforated Bottom 135mm (6")</td><td>14.42</td></tr><tr><td>JM344</td><td>½ Size Perforated Bottom 187mm (8")</td><td>14.42</td></tr><tr><td>JM094</td><td>¼ Size Perforated Bottom with Lid 65mm (2 ½")</td><td>14.42</td></tr><tr><td>JM096</td><td>¼ Size Perforated Bottom with Lid 130mm (5 1/8")</td><td>14.42</td></tr><tr><td>JM021</td><td>Extra Long Mini Bottom 73mm (3")</td><td>7.64</td></tr><tr><td>JM489</td><td>Full Size Lid</td><td></td></tr><tr><td>JM789</td><td>¾ Size Lid</td><td></td></tr><tr><td>JM389</td><td>½ Size Lid</td><td></td></tr><tr><td>See JM094 & JM096</td><td>¼ Size Lid</td><td></td></tr><tr><td>JM020</td><td>Extra Long Mini Lid</td><td></td></tr></table>	Item #	Description	Total loaded container weight (lbs)	JM440	Full Size Perforated Bottom 90mm (4 ¼")	21.46	JM441	Full Size Perforated Bottom 120mm (5 ½")	21.46	JM442	Full Size Perforated Bottom 135mm (6")	21.46	JM444	Full Size Perforated Bottom 187mm (8")	21.46	JM740	¾ Size Perforated Bottom 90mm(4 ¼")	14.42	JM741	¾ Size Perforated Bottom 120mm (5 ½")	14.42	JM742	¾ Size Perforated Bottom 135mm (6")	14.42	JM340	½ Size Perforated Bottom 90mm (4 ¼")	14.42	JM341	½ Size Perforated Bottom 120mm (5 ½")	14.42	JM342	½ Size Perforated Bottom 135mm (6")	14.42	JM344	½ Size Perforated Bottom 187mm (8")	14.42	JM094	¼ Size Perforated Bottom with Lid 65mm (2 ½")	14.42	JM096	¼ Size Perforated Bottom with Lid 130mm (5 1/8")	14.42	JM021	Extra Long Mini Bottom 73mm (3")	7.64	JM489	Full Size Lid		JM789	¾ Size Lid		JM389	½ Size Lid		See JM094 & JM096	¼ Size Lid		JM020	Extra Long Mini Lid	
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SterilContainer S System Accessories

Accessories	STERRAD 100NX EXPRESS Cycle
Stainless Steel baskets, basket lids, and dividers	Yes
Instrument Organization System (Silicone and Stainless Steel racks, brackets, holders, and clamps)	Yes
Silicone mats	Yes
Stainless Steel racks, trays, holders, clamps, brackets, and platforms	Yes

Note: Full, ¾, ½, and ¼ size containers have been validated with 5 stainless steel lumens per container system. The Extra Long Mini container has been validated with 2 stainless steel lumens per container system.

TABLE 2: SterilContainer S Compatible Containers in STERRAD NX Standard and Advanced Cycle

Item #	Description	Total loaded container weight (lbs)
JM440	Full Size Perforated Bottom 90mm (4 ¼")	21.46
JM441	Full Size Perforated Bottom 120mm (5 ½")	21.46
JM740	¾ Size Perforated Bottom 90mm (4 ¼")	13.85
JM741	¾ Size Perforated Bottom 120mm (5 ½")	13.85
JM742	¾ Size Perforated Bottom 135mm (6")	13.85
JM340	½ Size Perforated Bottom 90mm (4 ¼")	13.85
JM341	½ Size Perforated Bottom 120mm (5 ½")	13.85
JM094	¼ Size Perforated Bottom with Lid 65mm (2 ½")	13.85
JM096	¼ Size Perforated Bottom with Lid 130mm (5 1/8")	13.85
JM021	Extra Long Mini Bottom 73mm (3")	7.64
JM489	Full Size Lid	
JM789	¾ Size Lid	
JM389	½ Size Lid	
See JM094 & JM096	¼ Size Lid	
JM020	Extra Long Mini Lid	

Note: Full, ¾, ½, and ¼ size containers have been validated with 5 stainless steel lumens per container system. The Extra Long Mini container has been validated with 2 stainless steel lumens per container system.

TABLE 3: SterilContainer S Compatible Containers in STERRAD 100NX Standard Cycle

Item #	Description	Total loaded container weight (lbs)
JM440	Full Size Perforated Bottom 90mm (4 ¼")	21.46
JM441	Full Size Perforated Bottom 120mm (5 ½")	21.46
JM442	Full Size Perforated Bottom 135mm (6")	21.46
JM444	Full Size Perforated Bottom 187mm (8")	21.46
JM740	¾ Size Perforated Bottom 90mm(4 ¼")	13.85
JM741	¾ Size Perforated Bottom 120mm (5 ½")	13.85
JM742	¾ Size Perforated Bottom 135mm (6")	13.85
JM340	½ Size Perforated Bottom 90mm (4 ¼")	13.85
JM341	½ Size Perforated Bottom 120mm (5 ½")	13.85
JM342	½ Size Perforated Bottom 135mm (6")	13.85
JM344	½ Size Perforated Bottom 187mm (8")	13.85
JM094	¼ Size Perforated Bottom with Lid 65mm (2 ½")	13.85
JM096	¼ Size Perforated Bottom with Lid 130mm (5 1/8")	13.85
JM021	Extra Long Mini Bottom 73mm (3")	7.64
JM489	Full Size Lid	
JM789	¾ Size Lid	
JM389	½ Size Lid	
See JM094 & JM096	¼ Size Lid	

		<table><tr><td>JM020</td><td>Extra Long Mini Lid</td></tr></table> <p>Note: Full, ¾, ½, and ¼ size containers have been validated with 5 stainless steel lumens per container system. The Extra Long Mini container has been validated with 2 stainless steel lumens per container system.</p> <p>TABLE 4: SterilContainer S Compatible Containers in STERRAD 100NX Flex Cycle</p> <table><tr><th>Item #</th><th>Description</th><th>Total loaded container weight (lbs)</th></tr><tr><td>JM440</td><td>Full Size Perforated Bottom 90mm (4 ¼")</td><td>9.67</td></tr><tr><td>JM441</td><td>Full Size Perforated Bottom 120mm (5 ½")</td><td>9.67</td></tr><tr><td>JM442</td><td>Full Size Perforated Bottom 135mm (6")</td><td>9.67</td></tr><tr><td>JM444</td><td>Full Size Perforated Bottom 187mm (8")</td><td>9.67</td></tr><tr><td>JM740</td><td>¾ Size Perforated Bottom 90mm(4 ¼")</td><td>9.67</td></tr><tr><td>JM741</td><td>¾ Size Perforated Bottom 120mm (5 ½")</td><td>9.67</td></tr><tr><td>JM742</td><td>¾ Size Perforated Bottom 135mm (6")</td><td>9.67</td></tr><tr><td>JM340</td><td>½ Size Perforated Bottom 90mm (4 ¼")</td><td>9.67</td></tr><tr><td>JM341</td><td>½ Size Perforated Bottom 120mm (5 ½")</td><td>9.67</td></tr><tr><td>JM342</td><td>½ Size Perforated Bottom 135mm (6")</td><td>9.67</td></tr><tr><td>JM344</td><td>½ Size Perforated Bottom 187mm (8")</td><td>9.67</td></tr><tr><td>JM489</td><td>Full Size Lid</td><td></td></tr><tr><td>JM789</td><td>¾ Size Lid</td><td></td></tr><tr><td>JM389</td><td>½ Size Lid</td><td></td></tr></table> <p>Note: Full, ¾, and ½ size containers have been validated with 1 PTFE/PE lumen per container system.</p>	JM020	Extra Long Mini Lid	Item #	Description	Total loaded container weight (lbs)	JM440	Full Size Perforated Bottom 90mm (4 ¼")	9.67	JM441	Full Size Perforated Bottom 120mm (5 ½")	9.67	JM442	Full Size Perforated Bottom 135mm (6")	9.67	JM444	Full Size Perforated Bottom 187mm (8")	9.67	JM740	¾ Size Perforated Bottom 90mm(4 ¼")	9.67	JM741	¾ Size Perforated Bottom 120mm (5 ½")	9.67	JM742	¾ Size Perforated Bottom 135mm (6")	9.67	JM340	½ Size Perforated Bottom 90mm (4 ¼")	9.67	JM341	½ Size Perforated Bottom 120mm (5 ½")	9.67	JM342	½ Size Perforated Bottom 135mm (6")	9.67	JM344	½ Size Perforated Bottom 187mm (8")	9.67	JM489	Full Size Lid		JM789	¾ Size Lid		JM389	½ Size Lid	
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Sterilization process	STERRAD 100NX EXPRESS Cycle	STERRAD 200, NX (Standard and Advanced Cycles), 100NX (Standard and Flex Cycles)																																															
Material	Non-anodized aluminum	Non-anodized aluminum																																															
Container type	Perforated	Perforated																																															
Filter type	Polypropylene	Polypropylene																																															

PERFORMANCE DATA

Validation studies have been performed with the SterileContainer S System in the STERRAD 100NX EXPRESS Cycle. These validations were conducted by a qualified testing laboratory.

Performance Properties	Results
Sterilization Efficacy	Testing demonstrated a 6 log reduction to no growth in a half cycle validation. This testing supports a sterility assurance level (SAL) of 10^{-6} in a full cycle validation.
Whole Package Microbial Aerosol Challenge	After exposure to a defined amount of aerosol microorganisms contents maintained sterility
Event Related Sterility Maintenance	Testing demonstrated the ability to provide an effective barrier for maintaining sterility of the contents after processing followed by a 30 or 360 day event related storage under conditions which simulate hospital sterile

	package handling and storage conditions.
Material Compatibility	After 100 cycles of processing no visible or functional changes were observed
Biocompatibility	Cytotoxicity testing was conducted per ISO 10993-5 and showed no evidence of causing cell lysis or toxicity.
	A Hemolysis study was conducted per ASTM F756 and ISO 10993-4 and results were non-hemolytic

CONCLUSION

Performance testing demonstrates that the subject device is substantially equivalent to the predicate device.